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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

APR 2 2 1994

MEMORANDUM

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT:

JUSTIFICATION AND COST ESTIMATES FOR THE

MIXER/LOADER/APPLICATOR EXPOSURE MONITORING DATA REQUIRED TO SUPPORT THE REREGISTRATION OF ACEPHATE

FROM:

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TO:

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THRU:

Alan P. Nielsen, Section Head

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Larry C. Dorsey, Chief (V) Occupational and Residential Exposure Branch

Health Effects Division (7509C)

Please find the OREB review of

DP Barcode: not provided

Pesticide Chemical Code: 103301

EPA Req. No.: N/A

EPA MRID No.: N/A

Review Time: 1 day

PHED: No SRRD has requested that OREB provide justification regarding the mixer/loader/applicator data requirements presented in the acephate data call-in (DCI), 48-hour review.

Acephate is an insecticide applied to agricultural crops, forestry sites, ornamental plants (including greenhouse crops), and indoor areas. The toxicological concern for this product is based on a maternal NOEL in a rabbit developmental study indicating increased nasal discharge and abortion at 3 mg/kg/day. In addition, acephate is an organophosphate with a NOEL of 0.004 mg/kg/day for brain-cholinesterase inhibition. Because there is a high potential for exposure, mixer/loader/applicator data are required.

Because acephate is applied using a wide variety of equipment, it is suggested that the registrant propose study sites representing indoor and outdoor applications. The respective guideline numbers for the estimation of dermal and inhalation exposure at outdoor sites and the estimation of dermal and inhalation exposure at indoor sites, are 231, 232 and 233, 234.

The cost per guideline is estimated at \$125,000.00. In lieu of conducting the studies, the registrant may submit surrogate data in support of the reregistration requirements. Engineering controls, protective clothing and equipment, as well as risk mitigation procedures as appropriate for the current label should be discussed. Additional toxicity data and worker activity/use information which would clarify the actual exposure may also be submitted for evaluation. OREB suggests the registrant propose studies that group as many site/use pattern/application methods as possible providing that they are representational and estimate worst case scenarios.

cc: J. Evans, OREB
Correspondence File
Chemical File (103301)